Participants: Sebastian Comellas (SC)-Sinergium, AbdulAziz Hamid Almutairi (AA)-Arabio, Subhodeep Chakraborty (SCh)-Zydus, Cleber Gomes (CG)-Butantan, Rajinder Suri (RS), Sonia Villaseñor (SV)-DCVMN. **Meeting started at 12:05 pm CET and adjourned at 12:48 pm CET.**

SC welcomed the participants and presented the agenda.

Workshop Singapore 24-25 November 2023. RS clarified that the purpose is to organize a face-to-face meeting with a clear agenda, milestones and timelines to have a clarity of the purpose of the group and the contribution to the entire DCVMN member companies. Participants are requested to apply for their visas as soon as they receive the Visa invitation letters early next week.

1. Post Approval Changes (PACs). Regarding the training slides for the Moodle course, SC has shared 2 weeks ago the draft with all the Working Group members for comments and for participants to add content, but no feedback has been received until now. SC reviewed the different sections of the draft, emphasizing that he has included a section about the PAC in Latin-American countries, where he has experience. Mostly about the need to create an action plan on how to improve the situation in the different regions. SC added that there is the need to add slides about the situation in other regions like Africa and Asia. Being given that most of the DCVMN manufacturers are based in Asia, there should be a lot of information to be shared and added. He requested all WG members to add information.
The information already existing in the Moodle platform is not very complete, that is why there was a need to create this course.

SCh has already added some information and has started created a slides deck regarding the situation in Asia and few African countries. Which countries have adopted the TRS 993, which are not yet included in this presentation, and the differences we still need to work on, with real examples. SCh also recommended that, once a vaccine is WHO PQed, WHO always recommends a guideline, Version 7 for approved PQ vaccine, and then they ask for filing variation as per that NRA category. This could also be included. He requested SC to review the slides. Evaluation questions should also be included for the course final evaluation. AA requested SCh to share the slide and AA will include situation in Middle East and the feedback received by the NRAs.

CG and Monique Cruz will be also working on the Latin-American information, in particular about the situation in Brazil, mostly because ANVISA is the most recognized NRA in Latin-America. This will be for the presentation to be given in the Workshop in Singapore, but SC emphasized that this needs also to be included in the training slides deck.

SC Insisted to the group that we need to find concrete actions to move forward regarding PACs with timelines so that we can improve the situation and produce results useful for manufacturers.

RS mentioned that next month he will participate in a WHO meeting on WLPF (World Local Production Forum) and asked the group if they have any important message he could give at that time, to be sent that same day. AA said he would like to request more collaboration of WHO with Developing Countries. In the last 5 years WHO has become very busy and does not reply or contact with the NRAs. They are making training and workshops, but it has been decreasing. RS requested AA to send it by email to RS that same day.

2. Topics to work in 2024. SC had requested the IFPMA participants to suggest topics, but no response was received nor participants in this meeting. SC said that the results we could get could be totally different if we work along with IFPMA or alone. SCh said there was a proposal on electronic harmonization that WHO is about to implement as of Jan 2024. And about the CTD development. SCh also mentioned that nitrous amine impurities has also catch up with the vaccines and this could trouble the manufacturers. WHO has indicated that this is going to be their hot topic. And it is very confusing to have a risk valuation of raw materials wherein in vaccines there are multiple raw materials involved, then getting it tested, what should be the validations, what should be the limits. WHO has already started asking some information on nitrous amine analysis referring to EMA guidelines. So, this could be also very interesting topic because every manufacturer would like to understand that what is what would be the role and how basically to go about it for a vaccine with respect to nitrous amine.

SC said Pieter Neels (PN) had suggested a topic about Next Generation Sequencing (NGS), Gene Human Challenge trials and also about Real World Data. All of them are very interesting topics to start to work next year. During the meeting in Singapore, PN will give a detail explanation about them and in our meeting December we can discuss deeply about which topic we want to work next year, and also what IFMPA could be interested in, because they have worked in advance with these topics. It is important to work a topic in which we are able to publish a paper in a Journal. We should also consider the expertise of PN where he can help the WG.

CG mentioned that ANVISA had published recently a guideline under consultation regarding Real World Data. This information could be useful to work on. SC requested him to provide the group of the translation in English of this draft.

RS mentioned not to worry about IFPMA, we should really focus on what really concerns DCVMN. We can use their knowledge and expertise to guide if there is something missing or needs to be added.

SCh said the success will depend only on the participation of all members.

3. SC emphasized that we need to take advantage of the Face-to-Face workshop to improve our relationship and define concrete ideas to move forward with the ideas to work regarding PAC and other topics we want to make in the future.
RS suggested SC not to wait for anybody who is not responding and move forward.

Sebastian Comellas
Chair of the Regulatory WG

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